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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/655,093	09/04/2003	Yutaka Umehara	302962 81476	6886

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EXAMINER

WARE, DEBORAH K

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 12/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

### Application No.

10/655,093

### Applicant(s)

YUTAKA UMEHARA ET AL

### Examiner

Deborah K. Ware

### Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 26 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Claims 1-21 are presented for examination on the merits.

#### ***Papers***

The Power of Attorney filed January 26, 2004, has been received and entered of record.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-21 are rendered vague and indefinite for the recitation of "a portion of a whole organ or a portion of a whole tissue" since it is unclear what portion of the organ or tissue is intended, or is it an amount which is intended? The metes and bounds of the claims can not be determined.

Claims 5-6 are lack clear antecedent basis for "converting" at line 1 since it is uncertain whether the converting recited in these claims is a separate converting step than what is being performed in claim 4. It is suggested to insert —said—before "converting" in claims 5-6 at each occurrence in line of each claim to clarify that "converting" as recited in claims 5-6 is intended to refer back to "converting" step as recited in claim 4. Also claim 4 is unclear since it is uncertain how the tissue powder is obtained by "converting". How is the step of "converting" being carried out per se?

Art Unit: 1651

Hence the claim 4 fails to recite clear and distinct process steps for carrying out the claimed method.

Also claim 7 is lacking of clear antecedent basis for the recitation of the term “sonicating” for similar reason as discussed above, thus, it is suggested to insert – said— before “sonicating” in claim 7.

Claim 8 is rendered vague and indefinite because it is unclear how “the tissue powder” as recited in the line 2 is obtained for soaking since sonicating is a technique used to obtain “the tissue powder” by sonicating the ground particles. Hence before sonicating is performed there is no tissue powder but only ground particles. Therefore, claim 8 is indefinite for the recitation of “soaking the tissue powder” since it is unclear how it is obtained before grinding and sonicating the ground particles. Is the tissue powder not formed until after sonicating as set forth in claim 6?

Claim 14 is unclear for the recitation of “supporting cell growth” since it is unclear whether this is intended to mean merely a suspension culture medium or whether it is intended to mean an organ matrix for transplantation or as an organ replacement. The metes and bounds of the claim is unclear.

Claim 16 is further rendered vague and indefinite for the recitation of “at least partially” since it is unclear which part would not constitute the biological material.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

Art Unit: 1651

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Brekke et al (A) or Badylak et al (B), both cited on enclosed PTO-892 Form.

Claims are drawn to a cell culture matrix composition comprising a tissue powder such as bone and the composition further comprising a medium.

Brekke et al teach a cell culture matrix composition comprising a tissue powder such as bone and the composition further comprising a medium. Note column 15, lines 45-50, column 1, lines 10-20, and line 67 and column 7, lines 15-16. Also note the abstract and column 11, lines 34-40.

Badylak et al teach a cell culture matrix composition comprising a tissue powder such as bone and the composition further comprising a medium. Note column 1, line 66 and column 2, lines 40-60 and column 3, lines 25-53.

The claims are identical to the cited disclosures and are therefore considered to be anticipated by the cited prior art, Brekke et al and Badylak et al.

Claims 4-5, 9, 11, and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Badylak et al, as cited above.

Claims are drawn to a method for producing tissue powder comprising isolating tissue or organ as a biological material and converting it to tissue powder.

Badylak et al teach a method for producing tissue powder comprising isolating tissue or organ as a biological material and converting it to tissue powder. Also they teach method includes grinding, material selected from intestine, and freezing material as well as reducing to material to smaller pieces. Note abstract and column 1,

Art Unit: 1651

lines 65-67 and column 2, lines 40-60 and column 3, lines 10-60 and column 4, lines 10-15.

The claims are identical to the cited disclosure and are therefore considered to be anticipated by the cited prior art, Badylak et al.

Claims 14-16 and 19-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Brekke et al, cited above.

Claims are drawn to a method of supporting cell growth comprising providing cells and suspending cells in a medium with a tissue powder derived from biological material.

Brekke et al is discussed above, but also note column 14, all lines and column 15, lines 1-50.

The claims are identical to the cited disclosure and are therefore considered to be anticipated by the cited prior art, Brekke et al.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

Art Unit: 1651

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-21 are further rejected under 35 U.S.C. 103(a) as being unpatentable over Brekke et al in view of Badylak et al, Weiss et al (C), and Vail et al (D), all cited on enclosed PTO-892 Form.

Claims are discussed above.

Brekke et al and Badylak are discussed above.

Weiss et al teach perfusion technique, note column 43, lines 54-57.

Vail et al teach sonicating techniques, note column 4, lines 30-40.

The claims differ from Brekke et al in that sonicating techniques nor perfusion technique are clearly disclosed.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to provide for a cell culture matrix composition comprised of biological material using a tissue powder prepared by isolating the material and

Art Unit: 1651

converting it to powder as disclosed by Brekke et al and Badylak using sonication and perfusion techniques as disclosed by Weiss et al and Vail et al in order to support cell growth for transplantation. The process steps employed are clearly taught, or at least suggested by the cited prior art combination. The cell matrix composition is either clearly disclosed or at least suggested by the cited prior art. Brekke et al and Badylak both teach such compositions and methods of their preparation and using them to support cell growth. To replace media for supporting cell growth is clearly within the skill of an ordinary artisan. Further, to use a low pressure tank for drying the material as disclosed by Brekke et al and Badylak is an obvious modification of the cited prior art. One of skill would have been motivated by the combined teachings of the cited prior art to obtain the cell matrix composition and using the methods of the cited prior art to form tissue powder and support cell growth thereby using the matrix for transplantation. Clearly one of skill would have expected successful results and the claims are rendered prima facie obvious in the absence of clear and convincing evidence to the contrary.

All claims fail to be patentably distinguishable over the state of the art discussed above and cited on the enclosed PTO-892 and/or PTO-1449. Therefore, the claims are properly rejected.

The remaining references listed on the enclosed PTO-892 and/or PTO-1449 are cited to further show the state of the art.

No claims are allowed.



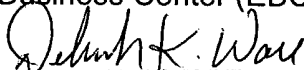
Art Unit: 1651

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah K. Ware whose telephone number is 571-272-0924. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free).

  
**DEBORAH K. WARE**  
**PATENT EXAMINER**

Deborah K. Ware  
December 11, 2004